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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,170	03/26/2004	Stephen Yencho	152	8001

7590

04/19/2005

Brian A. Schar
Chief Patent Counsel
Cardica, Inc.
900 Saginaw Drive
Redwood City, CA 94063

EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/810,170

Applicant(s)

YENCHO ET AL.

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/26/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-8, 10-12, and 14-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 9, 11, 17, 21, and 22 of U.S. Patent No. 6776785. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are merely broader than the patent claims. The structural limitations as set forth in the application are also claimed in the patent, i.e., a superelastic device body having an insertion configuration and a tissue holding configuration, and inner flange having a plurality of inner flange members, an outer flange having a plurality of outer flange members, and wherein at least a portion of the body between the inner flange and the outer flange maintains a substantially constant diameter in both the insertion configuration and the tissue holding configuration.

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3. Claims 9, 13, and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 9, 11, 17, 21, and 22 of U.S. Patent No. 6776785 in view of Berreklouw WO 00/44311. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations as set forth in the application are also claimed in the patent, i.e., a superelastic device body having an insertion configuration and a tissue holding configuration, and inner flange having a plurality of inner flange members, an outer flange having a plurality of outer flange members, and wherein at least a portion of the body between the inner flange and the outer flange maintains a substantially constant diameter in both the insertion configuration and the tissue holding configuration.

4. The difference between claims of the instant application and the patent claims are the number of the inner flange members are equal to the number of the outer flange members.

5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have equal numbers of inner and outer flange members as recited in the claim because the particulars of the numbers of inner and outer flange members are a mere design choice obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of the flanges are of importance or solve a state problem or provide an advantage over the prior art. Furthermore, it is known to have equal numbers of flanges as evidenced by Berreklouw. Furthermore, it would have been obvious to one having ordinary skill in the

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art to use equal number of flanges to distribute the clamping pressure supplied by the device to a target vessel when the device is in its unexpanded configuration.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-8, 10, 11, 13-21 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Berreklouw WO 00/44311.

8. As to claims 1-8, 10, 11, and 13-15, Berreklouw teaches a one-piece anastomosis device for connecting a graft vessel to a target vessel, comprising a body formed from superelastic material, the body deformable from a constrained configuration to an unconstrained configuration (figs. 2a, 2b, 11a, & 11b); a plurality of inner flange member forming an inner flange and a plurality of outer flange members forming an outer flange; and wherein at least a portion of the body between the inner flange and the outer flange has substantially the same diameter in both the constrained configuration and the unconstrained configuration; wherein the portion of the body between the inner flange and the outer flange that maintains a substantially constant diameter in both the constrained configuration and the unconstrained configuration includes a substantially rigid ring (fig. 6); wherein at least one of the inner flange

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members is substantially blunt; wherein at least one of the outer flange member is substantially blunt; wherein at least one of the inner flange member substantially does not pierce the target vessel when the body is in the unconstrained configuration; wherein at least one of the outer flange member substantially does not pierce the target vessel when the body is in the unconstrained configuration; wherein the superelastic material is nickel-titanium alloy (pg. 7, lines 20-21); and wherein the number of inner flange member is equal to the number of the outer flange members.

Fig 2a

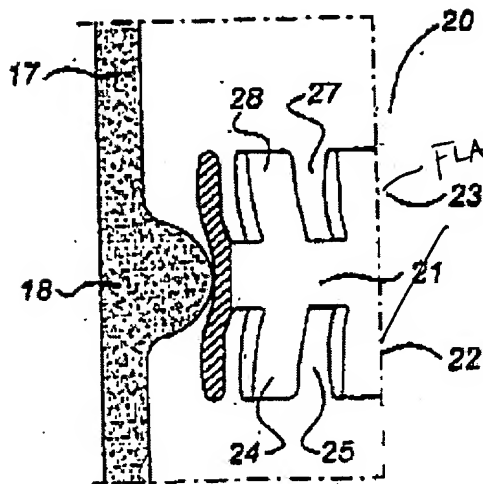


Fig 2b

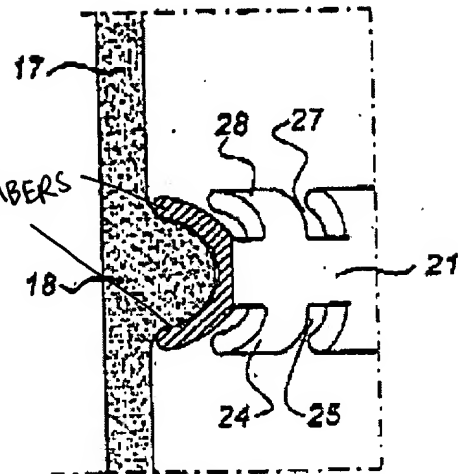


Fig 11a

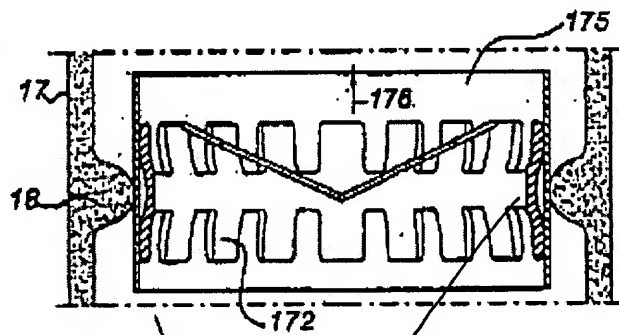
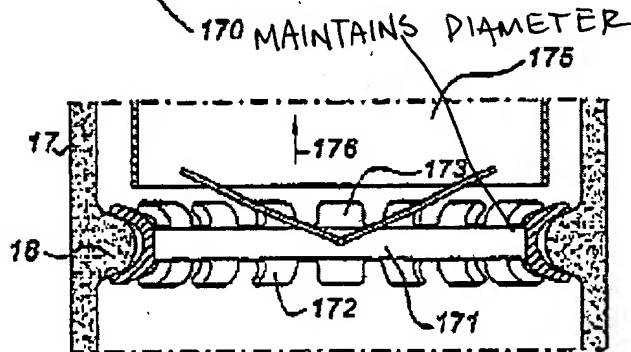
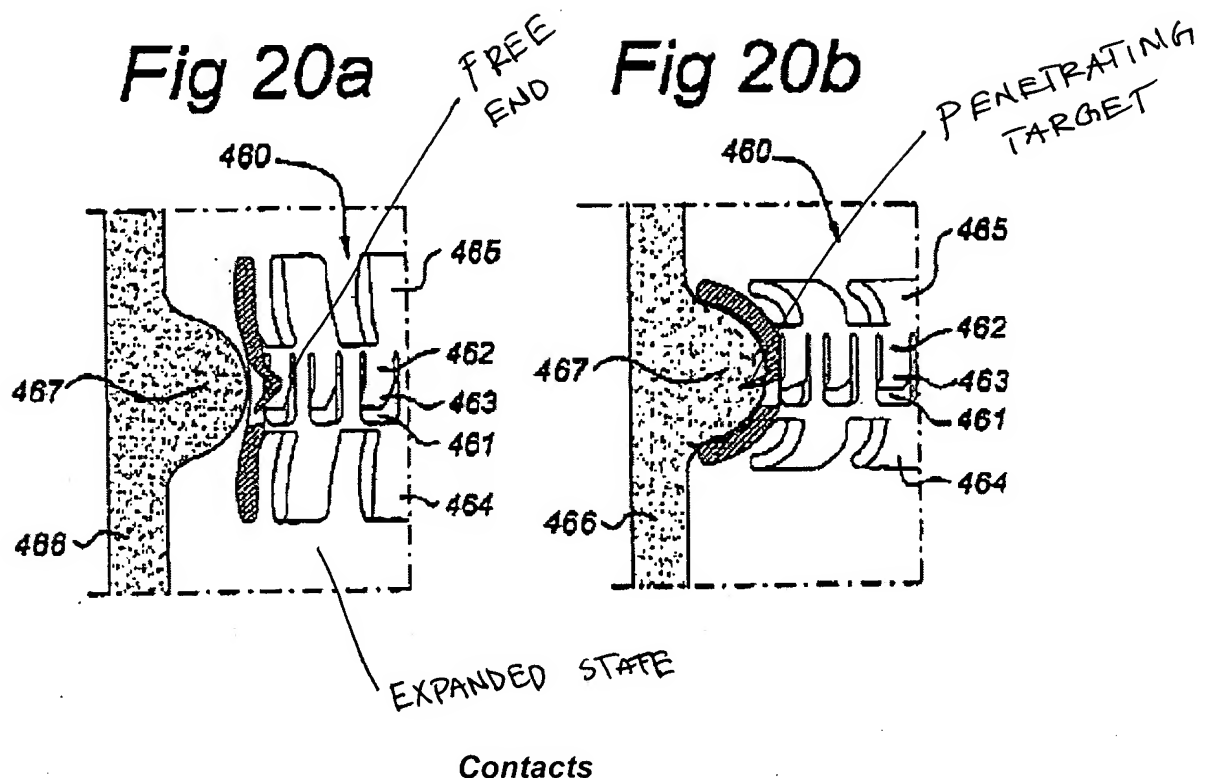


Fig 11b



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9. As to claims 16-21 and 23, Berreklouw teaches an anastomosis device for connecting a graft vessel to a target vessel, comprising: a open central structure; a plurality of first flange members extending from the central structure and movable from an insertion state to an expanded state; and a plurality of second flange member extending from the central structure and movable from an insertion state to an expanded state, at least one second flange member having a free end; wherein at least one free end is oriented generally toward at least one first flange member when the first flange members and second flange members in the expanded state; wherein at least one free end is pointed, whereby the pointed free end penetrates the target vessel; wherein at least one free end is pointed, whereby the pointed free end penetrates the graft vessel; wherein at least one free end is angled relative to a remainder of the corresponding second flange member (figs. 20a & 20b); wherein the central structure has a substantially fixed perimeter; wherein the central structure is a substantially rigid ring; and wherein the number of first flange members is equal to the number of the second flange members (fig. 6).



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER